Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102
(973) 286-6700

Attorneys for Plaintiffs
Sumitomo Dainippon Pharma Co., Ltd.
and Sunovion Pharmaceuticals Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUMITOMO DAINIPPON PHARMA CO., LTD. and SUNOVION PHARMACEUTICALS INC., Plaintiffs, v. EMCURE PHARMACEUTICALS USA, INC. and EMCURE PHARMACEUTICALS LTD., Defendants.	**Civil Action No. 15-280 (SRC)(CLW)** **(Filed Electronically)**
SUMITOMO DAINIPPON PHARMA CO., LTD. and SUNOVION PHARMACEUTICALS INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	**Civil Action No. 15-6401 (SRC)(CLW)** **(Filed Electronically)**

FINAL JUDGMENT AND ORDER OF PERMANENT INJUNCTION

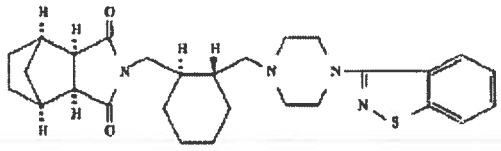
WHEREAS, Defendants Emcure Pharmaceuticals USA, Inc. and Emcure Pharmaceuticals, Ltd. (collectively, "Emcure") submitted Abbreviated New Drug Application No. 208058 ("Emcure's ANDA") seeking approval to engage in the commercial manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States of generic lurasidone hydrochloride tablets 20 mg, 40 mg, 60 mg, and 80 mg for treatment of schizophrenia and depressive episodes associated with Bipolar I Disorder (bipolar depression), as monotherapy and as adjunctive therapy with lithium or valproate (collectively "Emcure's ANDA Products") prior to the expiration of U.S. Patent No. 5,532,372 ("the '372 patent");

WHEREAS, Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, "Teva") submitted Abbreviated New Drug Application No. 208060 ("Teva's ANDA") seeking approval to engage in the commercial manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States of generic lurasidone hydrochloride tablets 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg for treatment of schizophrenia and depressive episodes associated with Bipolar I Disorder (bipolar depression), as monotherapy and as adjunctive therapy with lithium or valproate (collectively "Teva's ANDA Products") prior to the expiration the '372 patent;

WHEREAS, Plaintiffs Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. (collectively, "Sunovion") brought Civil Action No. 15-280 against Emcure, alleging, among other things, that the submission of Emcure's ANDA and

Emcure's ANDA Products infringe Claim 14 of the '372 patent, and Civil Action No. 15-6401 against Teva, alleging, among other things, that the submission of Teva's ANDA and Teva's ANDA Products infringe Claim 14 of the '372 patent;

WHEREAS, on November 15, 2016, this Court issued an Opinion and Order construing the following term of Claim 14: "[t]he imide compound of the formula:



," as "lurasidone, lurasidone's enantiomer, as well as mixtures of these enantiomers" ("the *Markman* Decision") [D.I. 106];

WHEREAS, Emcure and Teva have respectively agreed to stipulate that, under the Court's construction in the *Markman* Decision, the submission of Emcure's ANDA and Teva's ANDA to the United States Food and Drug Administration ("FDA") for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States of Emcure's ANDA Products and Teva's ANDA Products before the expiration of the '372 patent were each an act of infringement of Claim 14 of the '372 patent under 35 U.S.C. § 271(e)(2)(A);

WHEREAS, Sunovion, Emcure, and Teva have agreed to enter into a final judgment that will permit Emcure and/or Teva to seek an appeal of the *Markman* Decision ("the Appeal"); and

WHEREAS, Sunovion, Emcure, and Teva have agreed to stipulate that Claim 14 of the '372 patent is valid and enforceable, and Emcure and Teva have further agreed that they will not, whether directly or indirectly, challenge the patentability, validity, or enforceability of the '372 patent in this or any other action.

The Court, upon the stipulation and request of Sunovion, Emcure, and Teva, and for good cause shown, issues the following Final Judgment and Order of Permanent Injunction.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:

1. Sunovion, Emcure, and Teva do not contest personal jurisdiction in the United States District Court for the District of New Jersey for the purposes of the above-captioned actions only.

2. This Court retains exclusive jurisdiction to enforce or supervise performance under this Final Judgment and Order of Permanent Injunction.

3. Emcure and Teva concede that Claim 14 of the '372 patent is valid and enforceable.

4. Judgment is entered in favor of Sunovion and against Emcure and Teva on Emcure's and Teva's counterclaims that Claim 14 of the '372 patent is invalid.

5. Emcure, Teva, and their Affiliates shall not, directly or indirectly: (a) challenge the patentability, validity, or enforceability of the '372 patent; and/or (b) assist,

encourage, support, finance, or otherwise provide any information to, any third party for the purpose of challenging the patentability, validity, and/or enforceability of, and/or asserting noninfringement of the '372 patent.[1] Such challenges to the patentability, validity, or enforceability of the '372 patent include, but are not limited to, filing or maintaining (1) a request for *inter partes* review; (2) a request for reexamination; (3) any other pre- or post-grant proceeding in the United States Patent and Trademark Office; and (4) a declaratory judgment action.

6. Emcure and Teva stipulate that, under the Court's construction in the *Markman* Decision, the submission of Emcure's ANDA and Teva's ANDA to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States of Emcure's ANDA Products and Teva's ANDA Products before the expiration of the '372 patent were each an act of infringement of Claim 14 of the '372 patent under 35 U.S.C. § 271(e)(2)(A).

[1] For purposes of this Final Judgment and Order of Permanent Injunction, the term "Affiliate" shall mean any entity controlling, controlled by, or under common control with Emcure or Teva, but only as long as such control continues, where "control" means: (1) ownership of at least fifty percent (50%) of the equity or beneficial interest of such entity, or the right to vote for and/or appoint a majority of the board of directors or other governing body of such entity; and/or (2) the power to directly or indirectly direct or cause the direction of the management and policies of such entity by any means whatsoever.

7. Judgment of infringement of Claim 14 of the '372 patent is hereby entered in favor of Sunovion and against Emcure and Teva on Emcure's and Teva's counterclaims that Claim 14 is not infringed.

8. Nothing herein shall be deemed to be an admission, acceptance, or adoption by Emcure or Teva of the claim construction set forth in the *Markman* Decision.

9. Nothing herein shall preclude Emcure and Teva from pursuing the Appeal upon entry of this Final Judgment and Order of Permanent Injunction.

10. It is further stipulated and ordered that with the exception of paragraphs 3-5, Emcure and Teva do not waive any rights to seek modification of any portion of this Final Judgment, including the injunctive relief granted, to the extent the Court's claim construction is modified on appeal. Sunovion does not waive any rights to oppose any such request by Emcure and Teva.

11. In accordance with 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Emcure's ANDA No. 208058 shall be no earlier than January 2, 2019, the date of the expiration of the '372 patent, including any patent term extension and/or adjustment, and the expiration of pediatric exclusivity under 21 U.S.C. § 355a awarded to Sunovion. If Sunovion becomes entitled to any other exclusivities or patent term extension and/or adjustment that are not referenced herein, Sunovion and/or Emcure may apply to the Court for further relief as may be appropriate.

12. In accordance with 35 U.S.C. § 271(e)(4)(B), Emcure and its Affiliates, successors, partners, employees, agents, attorneys, and all those acting in privity or concert with them, and who have received actual notice of this injunction by personal service or otherwise, are hereby restrained and enjoined from engaging in the commercial manufacture, use, sale, offer for sale, and/or distribution within the United States, and/or importation into the United States of any lurasidone product that is the subject of Emcure's ANDA No. 208058 through and until January 2, 2019, the expiration of the '372 patent, including any patent term extension and/or adjustment, and the expiration of pediatric exclusivity under 21 U.S.C. § 355a awarded to Sunovion. If Sunovion becomes entitled to any other exclusivities or patent term extension and/or adjustment that are not referenced herein, Sunovion and/or Emcure may apply to the Court for further relief as may be appropriate.

13. In accordance with 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Teva's ANDA No. 208060 shall be no earlier than January 2, 2019, the date of the expiration of the '372 patent, including any patent term extension and/or adjustment, and the expiration of pediatric exclusivity under 21 U.S.C. § 355a awarded to Sunovion. If Sunovion becomes entitled to any other exclusivities or patent term extension and/or adjustment that are not referenced herein, Sunovion and/or Teva may apply to the Court for further relief as may be appropriate.

14. In accordance with 35 U.S.C. § 271(e)(4)(B), Teva and its Affiliates, successors, partners, employees, agents, attorneys, and all those acting in privity or

concert with them, and who have received actual notice of this injunction by personal service or otherwise, are hereby restrained and enjoined, from engaging in the commercial manufacture, use, sale, offer for sale, and/or distribution within the United States, and/or importation into the United States of any lurasidone product that is the subject of Teva's ANDA No. 208060 through and until January 2, 2019, the expiration of the '372 patent, including any patent term extension and/or adjustment, and the expiration of pediatric exclusivity under 21 U.S.C. § 355a awarded to Sunovion. If Sunovion becomes entitled to any other exclusivities or patent term extension and/or adjustment that are not referenced herein, Sunovion and/or Teva may apply to the Court for further relief as may be appropriate.

15. Nothing herein shall be deemed an admission of validity, enforceability or infringement of any claim other than Claim 14 of the '372 patent, or any other patent not asserted in the above-captioned actions.

16. Except as provided herein, all remaining claims and counterclaims as well as all pending motions between Sunovion, Emcure, and Teva are dismissed or denied without prejudice as moot, but may be reinstated at the request of the moving party should the case be remanded to this Court for further proceedings.

IT IS HEREBY STIPULATED:

Dated: February 7, 2017

By: s/ William C. Baton
Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700

Of Counsel:

Joseph M. O'Malley, Jr.
Preston K. Ratliff II
Bruce M. Wexler
PAUL HASTINGS LLP
200 Park Avenue
New York, NY 10166
(212) 318-6000

Attorneys for Plaintiffs
Sumitomo Dainippon Pharma Co., Ltd.
and Sunovion Pharmaceuticals Inc.

By: s/ David C. Kistler
Stephen M. Orlofsky
David C. Kistler
BLANK ROME LLP
New Jersey Resident Partners
301 Carnegie Center, 3rd Fl.
Princeton, NJ 08540

Attorneys for Defendants
Emcure Pharmaceuticals USA, Inc.
and Emcure Pharmaceuticals, Ltd.

By: s/ Michael E. Patunas
Michael E. Patunas
PATUNAS LAW LLC
24 Commerce Street, Suite 606
Newark, NJ 07102
(973) 396-8740

Of Counsel:

Ira J. Levy
Cynthia Lambert Hardman
GOODWIN PROCTER LLP
620 Eighth Avenue
New York, NY 10018
(212) 813-8800

Attorneys for Defendants
Teva Pharmaceuticals USA, Inc. and
Teva Pharmaceuticals Industries, Ltd.

IT IS SO ORDERED, this 13 day of February, 2017

Hon. Stanley R. Chesler, U.S.D.J.